IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Rao et al.

Serial No.: To be assigned

Filed: February 27, 2004

For: PERSISTENT EXPRESSION OF

CANDIDATE MOLECULE IN PROLIFERATING STEM AND PROGENITOR CELLS FOR DELIVERY OF

THERAPEUTIC PRODUCTS

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 2923-5456.1US

NOTICE OF EXPRESS M	[A]	LINC
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Christopher Haughton

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Date of Deposit with USPS: February 27, 2004

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are <u>not</u> being submitted pursuant to Pre-OG Notices http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/idswouscopies.htm (visited 9/15/2003). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission

that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

U.S. Patent No.	Publication Date	<u>Patentee</u>
US- 2002/0012660 A1	01/31/2002	Colman et al.
US- 2002/0037281 A1	03/28/2002	Davidson et al.
US- 4,350,687	09/21/1982	Lipton et al.
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Į	JS- 6,362,319 B1	03/26/2002	Lin et al.
J	JS- 6,436,387 B1	08/20/2002	Bauer et al.

Foreign Patent Documents

Document No.	Publication Date	<u>Patentee</u>
WO 96/04397	02/15/1996	Anvret et al.
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Other Documents

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ARBONES et al., "Gene Targeting in Normal Somatic Cells: Inactivation of the Interferon-y Receptor in Myoblasts," Nature Genetics, Vol. 6, Jan. 1994, pp. 90-159).

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LINNEY et al., "DNA Fragments from F9 PyEC Mutants Increase Expression of Heterologous Genes in Transfected F9 Cells," Cell, December 1983, pp. 693-99, Vol. 35.

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In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.:

2923-6033US

Serial No.:

60/496,830

Filing Date:

8/21/2003

Title:

GENETICALLY MODIFIED SOMATIC CELLS FOR

SUSTAINED SECRETION OF LYSOSOMAL PROENZYMES

DEFICIENT IN LYSOSOMAL STORAGE DISORDERS

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,

Krista Weber Powell Registration No. 47,867 Attorney for Applicant(s)

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Telephone: 801-532-1922

Date: February 27, 2004

KWP/bv

Enclosures: Form PTO-1449 or PTO/SB/08

Cited Documents

Document in ProLaw

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute	for form 1449A/PTO				Complete if Known
INFO	PRMATION	DI	SCLOSURE	Application Number	To be assigned
	TEMENT BY			Filing Date	
STATEMENT BY ATTECANT				First Named Inventor	Rao et al.
				. Group Art Unit	To be assigned
(use as many sheets as necessary)				Examiner Name	To be assigned
Sheet	1	of	4 .	Attorney Docket Number	2923-5456.1US

			U.S. PATENT D	OCUMENTS	
Examiner Initials *	Cite No.1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 2002/0012660 A1	01/31/2002	Colman et al.	
		US- 2002/0037281 A1	03/28/2002	Davidson et al.	
		US- 4,350,687	09/21/1982	Lipton et al.	
		US- 4,766,073	08/23/1988	Murray et al.	
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		US- 5,641,670	06/24/1997	Treco et al.	
	1	US- 5,650,148	07/22/1997	Gage et al.	

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Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶	
_		WO 96/04397	02/15/1996	Anvret et al.			

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

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Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE To be assigned Application Number Filing Date STATEMENT BY APPLICANT First Named Inventor Rao et al. Group Art Unit To be assigned (use as many sheets as necessary) Examiner Name To be assigned Sheet of 2923-5456.1US Attorney Docket Number

	,		U.S. PATENT I	OCUMENTS	
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·		US- 5,753,505	05/19/1998	Luskin	
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		US- 6,362,319 B1	03/26/2002	Lin et al.	
		US- 6,436,387 B1	08/20/2002	Bauer et al.	

		FOREIGN P.	ATENT DOCU	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ³ (if known)	Publication Date A		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		08298219 (Japanese Abstract)	05/12/1998	Mitsui		
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Examiner Signature	Date Considered	

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INIE	INFORMATION DISCLOSURE			Application Number	To be assigned	
				Filing Date		
STA	TEMENT I	BY A	PPLICANT	First Named Inventor	Rao et al.	
				Group Art Unit	To be assigned	
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Sheet	3	of	4	Attorney Docket Number	2923-5456.1US	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		AGAH et al., "Gene Recombination in Postmitotic Cells," J. Clin. Invest., July 1997, pp. 169-79, Vol. 100, No. 1.	
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<u>-</u>		COURT et al., "Genetic Engineering Using Homologous Recombination," Annu. Rev. Gener. 2002, 36:361-88.	
		HANSON et al., "Analysis of Biological Selections for High-Efficiency Gene Targeting," Mol. Cell. Biol., Jan. 1995, pp. 45-51.	
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•		LINNEY et al., "DNA Fragments from F9 PyEC Mutants Increase Expression of Heterologous Genes in Transfected F9 Cells," Cell, December 1983, pp. 693-99, Vol. 35.	
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		RAO et al., "Glial-Restricted Precursors Are Derived from Multipotent Neuroepithelial Stem Cells," Developmental Biology, 188:48-63, 1997.	
		SEDIVY, John M., "Can Ends Justify the Means?: Telomeres and the Mechanisms of Replicative Senescence and Immortalization in Mammalian Cells," Proc. Natl. Acad. Sci. USA, Vol. 95:9078-9081, Aug. 1998.	

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Signature	Considered	J

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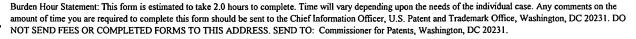
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			SCLOSURE	Filing Date			
STA	TEMENT B	YA	PPLICANT	First Named Inventor	Rao et al.		
				Group Art Unit	To be assigned		
	(use as many she	eets as i	necessary)	Examiner Name	To be assigned		
Sheet	4	of	4	Attorney Docket Number	2923-5456.1US		

	1	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner nitials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		SOMMER et al., "Neural Stem Cells and Regulation of Cell Number," Progress in Neurobiology, 66:1-18 (2002).	
		THOMAS et al., "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells," Cell, November 6, 1987, pp. 503-512, Vol. 51.	
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		YANEZ et al., "Differential Effects of Rad52p Overexpression on Gene Targeting and Extrachromosomal Homologous Recombination in a Human Cell Line," Nucleic Acids Research, 2002, Vol. 30, No. 3, pp. 740-748.	
·		YANEZ et al., "Influence of DNA Delivery Method on Gene Targeting Frequencies in Human Cells," Somatic Cell and Molecular Genetics, Vol. 25, No. 1, 1999, pp. 27-31.	
		YANEZ et al., "Therapeutic Gene Targeting," Gene Therapy, 1998, 5, pp. 149-159.	
		YANEZ et al., "Uracil Incorporation Into a Gene Targeting Construct Reduces the Frequency of Homologous and Nonhomologous Recombinants in Human Cells," Mutation Research 461, 2000, pp. 157-162.	

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